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Human Medicines Development and Evaluation

Public statement

Thelin (sitaxentan)

Withdrawal of the marketing authorisation in the European Union

On 10 August 2006 the European Commission granted a marketing authorisation for the whole European Union for Thelin (sitaxentan), an endothelin receptor antagonist used to treat adults (aged 18 years or over) with pulmonary arterial hypertension to improve exercise capacity (the ability to carry out physical activity) in patients with class III disease. Thelin was marketed in 16 EU Member States.

Thelin had been known to be associated with liver toxicity and since its initial marketing authorisation had been contra-indicated in patients with mild to severe hepatic impairment (Child-Pugh Class A-C) and elevated aminotransferases prior to initiation of treatment. On 12 December 2010, Pfizer, the marketing authorisation holder, requested the withdrawal of the marketing authorisation in the interest of patient safety. The decision to withdraw was further to new information on two cases of fatal liver injury.

This matter was discussed at the CHMP in December 2010. A transition plan was discussed and agreed with the marketing authorisation holder. The Agency published on 10 and 16 December 2010 two press releases[1] reflecting the current knowledge and discussions.

On 6 January 2011 the European Commission issued a decision confirming the withdrawal of the marketing authorization of Thelin. Pursuant to this decision the European Public Assessment Report for Thelin has been updated to reflect that the marketing authorisation is no longer valid.

Xavier Luria
Safety and Efficacy of Medicines

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http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2010/12/news_detail_001161.jsp&murl=menus/news_and_events/news_and_events.jsp&mid=WC0b01ac058004d5c1

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2010/12/news_detail_001168.jsp&murl=menus/news_and_events/news_and_events.jsp&mid=WC0b01ac058004d5c1

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8613
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union